510(K) Summary

Disc-O-Tech Medical Technologies Ltd.
Fixion® Dynamic Hip Screw System (Fixion® DHS)

Company Name

Disc-O-Tech Medical Technologies, Ltd.

3 Hasadnaot St., Herzliya

Israel, 46728

Submitter's Name and Contact Person

Yael Rubin

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Date Prepared

April 2003

Trade/Proprietary Name

Fixion® Dynamic Hip Screw System (Fixion® DHS)

Classification Name

Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

21 CFR 888.3030

Class II

Predicate Devices

- Fixion Interlocking Proximal Femoral Intramedullary Nailing System (K010988, K012967, K023437) by Disc-O-Tech Medical Technologies, Ltd.
- Gotfried PC.C.P (K983814) by Efratgo.
- Vari-Angle Hip Screw System - VHS (K964880) by Biomet.
- TK2™ Compression Hip Screw System (K972629) by DePuy ACE
- Fixion Interlocking Intramedullary Nailing System (K002873, K013449, K023437) by Disc-O-Tech Medical Technologies, Ltd.

Performance Standards

The following standards were referred:

- ASTM F 382 – 99: Standard Specification and Test Method for Metallic Bone Plates
- ASTM F 384 – 00: Standard Specification and Test Method for Metallic Angled Orthopedic Fracture Fixation Devices
- Guidance Document for Testing Non-Articulating, "Mechanically Locked", Modular Implant Components (Draft), ORDB/DGRD/CDRH/FDA, May 1, 1995
- The Fixion DHS implants are manufactured from Titanium and Titanium alloy, which meet the requirements of ASTM F 1472 – 02, ASTM F 136 – 02, and ASTM F 67 – 00.
- The Fixion DHS System accessories incorporate surgical grade Stainless Steel (complying with ASTM F 899 – 02, ASTM F 1586 – 95), Silicone and Celeron (complying with ISO 16061).

Intended Use

The *Fixion Dynamic Hip Screw System* (Fixion DHS) is intended for use in fixation of fractures in the proximal femur. The Fixion DHS is indicated for use in pertrochanteric, intertrochanteric, and base of femur neck fractures.

The Fixion DHS can be implanted in an open or in a minimally invasive approach.

K031401 3/3

System Description

The Fixion DHS System consists of the following components:

- Plate – a solid, titanium-made, component, incorporating holes for the insertion of the Hip Peg, Locking Pin and Screws. The Plate Body is shaped to comply with the bone curvature and the Barrel is located at 135° - 145° relative to the Plate Body.
- Hip Peg – a titanium-made tube with a distal expandable section, to enhance the abutment of the Hip Peg inside the femoral head. The expandable body ends with a conical shaped distal end.
- Locking Pin – a titanium-made pin. It is used to provide additional fixation of the fragment, if needed, and for stabilizing bone fragments in case of torsional instability
- Screws – titanium screws. Maximum of 3 - 7 Screws (Plate length dependant) can be used to attach the plate to the bone (the femur shaft) at its distal section.
- Instrumentation Set – a set of accessories to be used with the Fixion DHS implants. Accessories for both open and minimally invasive surgical approaches are available.
- Inflation Device (Pump) – a manual pump used to expand the Hip Peg.

Substantial Equivalence

The Fixion DHS intended use, design, materials, technological characteristics and principles of operation are substantially equivalent to those of Disc-O-Tech's Fixion Interlocking PF Intramedullary Nailing System (K010988, K012967, K023437) and Fixion Interlocking Intramedullary Nailing System (K002783, K013449, K023437), Gotfried PC.C.P (K983814), Biomet VHS (K964880) and DePuy ACE TK2 Compression Hip Screw System (K972629).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Mr. Yael Rubin
Director of Regulatory Affairs
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St. Herzliya
Israel, 46728

Re: K031401
Trade/Device Name: Fixion Dynamic Hip Screw System (Fixion DHS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: July 7, 2003
Received: July 9, 2003

Dear Mr. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K031401

Device Name: Fixion® Dynamic Hip Screw System (Fixion® DHS)

Indication for Use:

The Fixion Dynamic Hip Screw System ("Fixion DHS") is intended for use in fixation of fractures in the proximal femur. The Fixion DHS is indicated for use in pertrochanteric, intertrochanteric, and base of femur neck fractures.

The Fixion DHS can be implanted in either open or minimal invasive surgical approach.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over the Counter Use _____

(per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031401